

Application No. 10/053,053
Responsive to an Office Action dated March 2, 2010
Response filed June 2, 2010

REMARKS

This amendment is in response to the Office action dated March 2, 2010. Claim 1 has been amended. New claim 61 has been added. Claims 1-3, 10, 12-19, 21-40, 42-50 and 60-61 are pending in this application.

Claim Rejections – 35 USC §103

On page 2 of the action, claims 1, 12 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al., hereinafter "Lenker" (U.S. Patent No. 6,350,278) in view of Swanstrom (WO 99/33402). Applicant respectfully traverses the rejection.

In assessing the differences between the claim and the cited references, every feature of the claim must be disclosed or suggested in the cited references or known to one skilled in the art in making a *prima facie* case of obviousness. *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). A *prima facie* case of obviousness also requires a reasonable expectation of success in the modification or combination of references, which must be found in the cited references or must be known to one skilled in the art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Also, if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Furthermore, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Independent claim 1 as amended provides (emphasis added):

An apparatus for installing an implant in a hollow body organ having a vessel wall, including:

means for transporting said implant into said hollow body organ;

a removable expansion assembly releasably engageable with said implant, said removable expansion assembly including a plurality of peripheral struts extending generally parallel to a longitudinal axis and spaced angularly thereabout, said struts including like proximal ends and distal ends, said proximal ends being free of mechanical connection, said distal ends being secured together and connected to a tube, and a cap, said cap being mounted on a central strut slidably disposed within said tube, wherein said cap is movable between a first position, wherein said proximal ends are captured within said cap, and a second position, wherein said proximal ends are released from said cap;

means for dilating said expansion assembly and expanding a portion of said implant against said vessel wall;

means for fastening said portion of said implant to said vessel wall of said organ while said expansion assembly holds said portion against said vessel wall;

and

means for collapsing said expansion assembly and releasing said portion of said implant;

wherein said implant is disposed around the plurality of peripheral struts.

As provided in the claimed invention in independent claim 1, the implant is particularly situated relative to the expansion assembly to ensure that the implant's ends impinge against the arterial wall to enable fixation of the implant ends which is particularly useful, e.g., for fixating implants that have no inherent or embedded expansion or fixation characteristics.

The Office action points to Lenker to disclose a delivery device for positioning an intraluminal prosthesis in a vessel wall of an organ comprising an expansion assembly with proximal ends of struts 342 and cites Figures 23A-23B. Lenker, in col. 12, lines 1-3, does describe that a "retaining structure 340 comprises a plurality of individual resilient axial members 342 which are captured at their distal ends and an anchor 344." Lenker also further describes, in col. 12, lines 6-10 in reference to Figures 23A-23B, that the "axial elements 342 are spring-loaded so that when the anchor 344 is moved

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distally by advancing the shaft 350, as illustrated in FIG. 23b, the individual elements will spring radially apart at the distal end. In this way, prosthesis P can be released from the retaining structure 340." It is also noted that in FIG. 23a, the prosthesis P cannot be seen and in FIG. 23b with the axial elements sprung apart, the prosthesis P is then visible. Accordingly, Lenker's plurality of individual resilient axial members surrounds and retains Lenker's prosthesis. Conversely, the claimed invention provides that the implant is disposed around the plurality of peripheral struts. This difference is also particularly significant as one of ordinary skilled in the art would not modify Lenker to have its prosthesis be disposed around the plurality of individual axial members as Lenker's axial members would then fail to retain the prosthesis as Lenker's prosthesis would be free to expand without the retaining structure limiting such an expansion. Therefore, such a modification would also be contrary or unsatisfactory to Lenker's teaching.

The action uses Swanstrom to teach a means for fastening. However, Swanstrom does not cure the above-noted deficiencies of Lenker as providing an implant disposed around the plurality of peripheral struts or a teaching or suggestion to make such a modification. Therefore, Lenker, Swanstrom or the combination thereof does not describe or suggest all the claim elements as provided in claim 1. Thus, in view of the foregoing, a *prima facie* case of obviousness is not established and hence claim 1 is believed to be patentable.

Claims 12 and 31-36 depend from independent claim 1. As indicated above, Applicant believes that independent claim 1 is allowable over Lenker in view of Swanstrom for the reasons stated. Since claims 12 and 31-36 depend from independent claim 1, and contain additional limitations that are patentably distinguishable over the references of record, claims 12 and 31-36 are also believed to be patentable.

Claim Rejections – 35 USC §103 (Continued)

On page 4 of the action, claims 2, 15 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,350,278) in view of

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Swanstom (WO 99/33402), as applied to claim 1 above, and further in view of Hughes et al. (U.S. Patent No. 4,728,328). Applicant respectfully traverses the rejection.

Claims 2, 15 and 24-25 depend from independent claim 1. As indicated above, Applicant believes that independent claim 1 is allowable over Lenker in view of Swanstom for the reasons stated. Hughes et al. does not cure the above-noted deficiencies of Lenker and Swanstom and thus a *prima facie* case of obviousness is not established. Therefore, since claims 12 and 31-36 depend from independent claim 1, and contain additional limitations that are patentably distinguishable over the references of record, claims 12 and 31-36 are also believed to be patentable.

Also, regarding claim 2, claim 2 recites that the implant comprises a tubular, sleeve-like component free of mechanical structure. The action points to Hughes et al. in reference to Figure 1 to show such an implant. However, the combination and operation of an implant free of mechanical structure with the expansion assembly of the claimed invention is particularly noteworthy. With the implant free of mechanical structure, the implant does not have inherent expansion characteristics and thus does not expand unless expanded by the struts of the expansion assembly as provided by the claimed invention. Conversely, the prosthesis or graft of Lenker relies on such a mechanical structure, e.g., a "tubular frame 12 is covered by an inner liner 18 and an outer liner 20", such that when the individual resilient axial members spring radially apart to release the prosthesis, the prosthesis due to it's mechanical structure, e.g., tubular frame 12, radially expands to contact the walls of the body lumen L. (See FIGs. 3-5 and col. 6, lines 56-62 and col. 7, lines 53-65). Therefore, such a modification to replace Lenker's prosthesis with the prosthesis of Hughes et al. would be contrary or unsatisfactory to Lenker's teaching and would make Lenker's device inoperable. Thus, in view of the foregoing, a *prima facie* case of obviousness is not established and hence claims **2, 15 and 24-25** are believed to be patentable.

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Claim Rejections – 35 USC §103 (Continued)

On page 5 of the action, claims 3 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,350,278), Swanstrom (WO 99/33402), and Hughes et al. (U.S. Patent No. 4,728,328), as applied to claim 2 and 15 above, and further in view of Cox et al. (U.S. Pub. No. 2003/0023301). Applicant respectfully traverses the rejection.

Claims 3 and 16-19 depend from dependent claim 2 and independent claim 1. As indicated above, Applicant believes that independent claim 1 is allowable over Lenker in view of Swanstrom for the reasons stated. Also, as noted above, Hughes et al. does not cure the above-noted deficiencies of Lenker and Swanstrom with regards to claims 1 and 2. Similarly, Cox et al. does not cure the above-noted deficiencies of Lenker, Swanstrom and Hughes et al. with regards to claims 1 and 2 and thus a *prima facie* case of obviousness is not established. Therefore, since claims 3 and 16-19 depend from claims 1 and 2, and contain additional limitations that are patentably distinguishable over the references of record, claims 3 and 16-19 are also believed to be patentable.

Claim Rejections – 35 USC §103 (Continued)

On page 6 of the action, claims 10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,350,278) and Swanstrom (WO 99/33402), as applied to claim 1 above, and further in view of Levinson et al. (U.S. Patent No. 6,537,296). Also, claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker in view of Swanstrom (WO 99/33402) and Levinson et al. (U.S. Patent No. 6,537,296). Applicant respectfully traverses these rejections.

The action indicates that Lenker and Swanstrom disclose the claimed device except for the struts being urged in a proximal direction in order to thereby compress the peripheral struts axially by impinging on the proximal ends, and the expansion assembly being received within a confinement tube. The action further uses Levinson et al. to describe a plurality of peripheral struts **10** with proximal ends (near **40**) and distal ends (near **46**), and a stop **16** mounted on a central strut **12** slidably disposed

within said tube, wherein said stop is movable between a first position, wherein said proximal ends are abutting said stop, wherein the stop impinges on said proximal ends to compress struts axially, and a second position wherein said proximal ends are not abutting said stop, a means for dilating 44 said expansion assembly against said vessel wall and means for collapsing said expansion assembly (Figures 27A-C). The action concludes that it would have been obvious to one of ordinary skill in the art at the time of invention to provide struts being urged in a proximal direction in order to thereby compress the peripheral struts axially by impinging on the proximal ends, as taught by Levinson et al., to Lenker and Swanstrom in order to selectively collapse and expand the assembly if desired.

However, such a modification of Lenker and Swanstrom by Levinson et al. would be contrary to the operation and teaching of Lenker and Swanstrom. In particular, modifying Lenker and Swanstrom with the suggested teachings of Levinson et al. would prevent the individual elements of Lenker's device from springing radially apart at the distal end and prevent the prosthesis P from being released from the retaining structure. Thus, since such a modification would render the relied upon prior art unsatisfactory or change the principle operation of the relied upon prior art, *prima facie* case of obviousness is not established and hence claims 10, 13-14 and 60 are believed to be non-obvious in view of Lenker, Swanstrom and Levinson et al.

Additionally, claims 10 and 13-14 depend from independent claim 1. As indicated above, Applicant believes that independent claim 1 is allowable over Lenker in view of Swanstrom for the reasons stated. Levinson et al. does not cure the above-noted deficiencies of Lenker and Swanstrom. Since claims 10 and 13-14 depend from independent claim 1, and contain additional limitations that are patentably distinguishable over the references of record, claims 10 and 13-14 are also believed to be patentable.

Claim Rejections – 35 USC §103 (Continued)

On page 7 of the action, Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,350,278), Swanstrom (WO 99/33402), and Hughes et al. (U.S. Patent No. 4,728,328), as applied to claim 2 above,

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and further in view of Trescony et al. (U.S. Patent No. 5,653,745). On page 8 of the action, Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,350,278), Swanstrom (WO 99/33402), and Hughes et al. (U.S. Patent No. 4,728,328), as applied to claim 25 above, and further in view of Chevillon et al. (U.S. Patent No. 6,248,116). Also, on page 8 of the action, Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,350,278), Swanstrom (WO 99/33402), and Hughes et al. (U.S. Patent No. 4,728,328), as applied to claim 2 above, and further in view of White et al. (U.S. Pub. No. 2006/0015176). Applicant respectfully traverses these rejections.

Claims 21-23 and 26-30 depend from dependent claim 2 and independent claim

1. As indicated above, Applicant believes that independent claim 1 is allowable over Lenker in view of Swanstrom for the reasons stated. Also, as noted above, Hughes et al. does not cure the above-noted deficiencies of Lenker and Swanstrom with regards to claims 1 and 2. Similarly, Trescony et al., Chevillon et al., and White et al. do not cure the above-noted deficiencies of Lenker, Swanstrom and Hughes et al. with regards to claims 1 and 2 and thus a prima facie case of obviousness is not established. Therefore, since claims 21-23 and 26-30 depend from claims 1 and 2, and contain additional limitations that are patentably distinguishable over the references of record, claims 21-23 and 26-30 are also believed to be patentable.

Claim Rejections – 35 USC §103 (Continued)

On page 9 of the action, Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,350,278) in view of Swanstrom (WO 99/33402), as applied to claim 36 above, and further in view of Haber et al. (U.S. Patent No. 5,201,743). Applicant respectfully traverses these rejections.

Claims 37-39 depend from independent claim 1. As indicated above, Applicant believes that independent claim 1 is allowable over Lenker in view of Swanstrom for the reasons stated. Haber et al. does not cure the above-noted deficiencies of Lenker and Swanstrom and thus a prima facie case of obviousness is not established. Therefore,

since claims 37-39 depend from independent claim 1, and contain additional limitations that are patentably distinguishable over the references of record, claims 37-39 are also believed to be patentable.

Claim Rejections – 35 USC §103 (Continued)

On page 10 of the action, Claims 40 and 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,350,278) in view of Cox et al. (U.S. Pub. No. 2003/0023301). Applicant respectfully traverses these rejections.

Independent claim 40 provides (emphasis added):

A removable expansion assembly for dilating a surgical implant within a hollow body organ, including:

a plurality of peripheral struts, said struts having a relaxed state in which said peripheral struts extend generally parallel to a longitudinal axis and are spaced angularly thereabout, said peripheral struts including proximal ends, said proximal ends being free of mechanical connection;
said plurality of peripheral struts being removably disposed within said surgical implant; and

means for urging said peripheral struts to a bowed state, wherein said peripheral struts expand radially outwardly from said longitudinal axis, to thereby dilate said surgical implant.

As provided in the claimed invention in independent claim 40, the implant is particularly situated relative to the plurality of peripheral struts to ensure that the implant's ends impinge against the arterial wall to enable fixation of the implant ends which is particularly useful, e.g., for dilating and fixating implants that have no inherent or embedded expansion or fixation characteristics.

The Office action indicates that Lenker "discloses said plurality of peripheral struts #342 being removably disposed within said surgical implant, or within the lumen of the implant P (Figure 23B)." However, Lenker describes that a "retaining structure 340 comprises a plurality of individual resilient axial members 342 which are captured at

their distal ends and an anchor 344" and that the "axial elements 342 are spring-loaded so that when the anchor 344 is moved distally by advancing the shaft 350, as illustrated in FIG. 23b, the individual elements will spring radially apart at the distal end. In this way, prosthesis P can be released from the retaining structure 340." It is also noted that in FIG. 23a, the prosthesis P cannot be seen and in FIG. 23b with the axial elements sprung apart, the prosthesis P is then visible. (See col. 12, lines 1-10 and Figures 23A-23B). Accordingly, Lenker's prosthesis is retained by the plurality of individual resilient axial members and the individual resilient axial members are not removably disposed within said surgical implant, or within the lumen of the implant P as so indicated by the action. Thus, Lenker fails to describe or suggest the claimed limitation of the plurality of peripheral struts being removably disposed within said surgical implant. This difference is also particularly significant as one of ordinary skilled in the art would not modify Lenker to have it's prosthesis be disposed around the plurality of individual axial members as Lenker's axial members would then fail to retain the prosthesis as Lenker's prosthesis would be free to expand without the retaining structure limiting such expansion. Therefore, such a modification would also be contrary or unsatisfactory to Lenker's teaching.

The action does not use Cox et al. in the rejection of claim 40. However, Cox et al. does not cure the above-noted deficiencies of Lenker as providing the plurality of peripheral struts being removably disposed within said surgical implant or a teaching or suggestion to make such a modification. Therefore, Lenker, Cox et al. or the combination thereof does not describe or suggest all the claim elements as provided in claim 40. Thus, in view of the foregoing, a *prima facie* case of obviousness is not established and hence claim 40 is believed to be patentable.

Claims 42-50 depend from independent claim 40. As indicated above, Applicant believes that independent claim 40 is allowable over Lenker in view of Cox et al. for the reasons stated. Since claims 42-50 depend from independent claim 40, and contain additional limitations that are patentably distinguishable over the references of record, claims 42-50 are also believed to be patentable.

NEW CLAIM

New claim 61 describes other aspects of the invention. For example, new claim 61 provides a stentless endograph disposed around the plurality of peripheral struts. The cited references do not describe or suggest such a removable expansion assembly with the recited features in new claim 61. Also, since claim 61 depends from independent claim 60 and thus incorporates the features recited in corresponding claim and contain additional limitations that, when considered as a whole are patentably distinguishable over the references of record, claim 61 is believed to be patentable.

New claim 61 also depends from a claim readable on the elected invention and/or is directed to an apparatus for installing an implant, classified in class 606, subclass 191. Thus, new claim 61 is believed readable on the elected invention. If, however, based on this amendment the Examiner believes a different election/restriction requirement is required and/or selection of claims, Applicant reserves the right to change/traverse the election of species and claims directed thereto. Additionally, the new claims find full support in the original specification. Accordingly, Applicant submits that no new matter has been added.

Conclusion

Although the present paper may include a combination of alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding that previously pending claims in this application are not patentable over the cited references. Rather, any alterations and/or characterizations are made to facilitate prosecution of this application. Applicants reserve the right to pursue any previously pending, or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or in any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

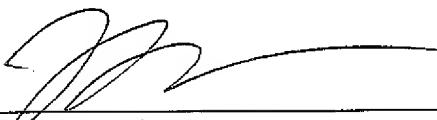
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Applicants submit that all of the Examiner's rejections have been addressed and overcome, and that all claims are allowable over the art of record. Applicants have submitted amendments and arguments believed to be sufficient to overcome all of the outstanding rejections. Consequently, Applicants have not advanced every argument for the allowability of the claims over the references of record. As such, Applicants do not acquiesce to any of the Examiner's statements or characterizations not specifically traversed. Should the Examiner believe that any outstanding issues are resolvable in an Examiner's Amendment, the Examiner is invited to contact the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 01-2215.

Respectfully submitted,
APPLIED MEDICAL RESOURCES

BY



Patrick Ikehara
Registration No. 42,681
Telephone: (949) 713-8327